Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

Title of Trial: Safety and Immunogenicity of the inactivated whole virus cell-derived H5N1 vaccine in the phase II clinical trials, Vabiotech, Vietnam

Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov): No: 1U01CI000347-01

Authors/sponsors: Thu Van Nguyen/ Government of Vietnam and HHS/CDC, US

Study Design (including the phase of clinical trial): The phase II trial


Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector): Inactivated whole virion adjuvanted vaccine produced in primary monkey kidney cells

Adjuvant: AL(OH)3
Delivery system/site: Intramuscularly

Doses (antigen and adjuvant, number of doses, intervals between administrations): 3.75, 7.5, 15, 30 and 45µg of HA per dose, two doses at day 0 and 28

Study population

Number of subjects involved: Adults   Age range: 18-45 years   Health status: Healthy volunteers

Special inclusion criteria:
Vital signs, especially blood pressure, in the acceptable range
HBV (-), HIV(-), HCV(-)
Stable medical conditions

• Exclusion Criteria
Immunosuppression
Acute or chronic diseases
Receipt of Immunoglobulin or any other vaccines during the past 2 weeks
Pregnant/baby breast feeding
History of SAEs for any vaccines.

Clinical Endpoints Assessed
Safety assessments:
Immunogenicity assessments: HI at day 0, 28 and 56
Imunoassay type
HI (type of RBC used): Horse Erythrocytes

Results

Safety:
• Reactogenicity: No SAE has been recorded in this study.
At the first dose, there were 32.88% subjects in phase II who had pain at injection site and extended to the day 2nd. Other symptoms were not seen in this study.
At the second dose, there were 13.21% subjects in phase II who had pain at injection site. Other symptoms were not seen in this study.
Immunogenicity

**HI or NT: HI**

**GMTs:**

**GMT Ratios (post:pre):**

**Per cent responding (4 fold increase):**

**Per cent responders at specified titer:**

HI ≥ 40 after doses:

1 dose 2 doses

with antigen of viruses from:

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**SRH: N/A**

Per cent with titre (in mm²)

Current status of the clinical trial (completed, ongoing, in preparation): Completed

Date envisaged for availability of results, if not yet available:

Planned time schedule for next phase of development:

- Phase 3 (it depends on the decision of MOH: July – September, 2010
- Registration and licensing: October – December, 2011.